



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: G. SCHMIDMAIER et al.

Confirmation No.: 8071

Application No.: 09/801,752

Group Art Unit: 1615

Filed: March 9, 2001

Examiner: H. Sheikh

For: BIOLOGICALLY ACTIVE IMPLANTS

Attorney Docket No.: 8932-148

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**FOURTH INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Pursuant to applicants' duty of disclosure under 37 C.F.R. § 1.56 and § 1.97(h), enclosed is a substitute Form PTO-1449, entitled "List of References Cited by Applicant, which lists 24 references in reverse chronological order, copies of which are enclosed for the Examiner's convenience. It is respectfully requested that these references be made of record in this application by the Examiner's completion and return of the substitute Form PTO-1449.

As this Information Disclosure Statement is being filed after receipt of the first office action on the merits, but before the mailing date of a final office action or notice of allowance, the fee for this submission pursuant to 37 C.F.R. §1.17(p) is believed to be \$180.00. Please charge this fee and any additionally required fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date November 6, 2003

*Brian M. Rothery*  
For: Brian M. Rothery

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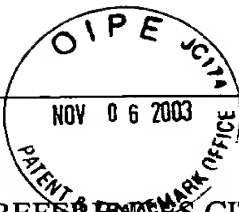
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Enclosures

DC1: 358794.1



**LIST OF REFERENCES CITED BY APPLICANT**  
(Use several sheets if necessary)

ATTY DOCKET NO.

**8932-148**

APPLICATION NO

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APPLICANT

**G. SCHMIDMAIER et al.**

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**U.S. PATENT DOCUMENTS**

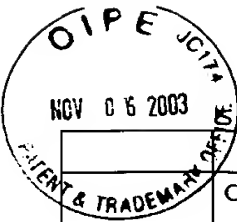
| *EXAMINER INITIAL |     | DOCUMENT NUMBER | DATE       | NAME               | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|-------------------|-----|-----------------|------------|--------------------|-------|----------|----------------------------|
|                   | A01 | 5,906,600       | 5/25/1999  | Bähr               | 604   | 265      |                            |
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|                   |     |                 |            |                    |       |          |                            |
|                   |     |                 |            |                    |       |          |                            |
|                   |     |                 |            |                    |       |          |                            |
|                   |     |                 |            |                    |       |          |                            |

**FOREIGN PATENT DOCUMENTS**

|  |     | DOCUMENT NUMBER | DATE     | COUNTRY | CLASS | SUBCLASS | TRANSLATION<br>* Abstract Only |    |
|--|-----|-----------------|----------|---------|-------|----------|--------------------------------|----|
|  |     |                 |          |         |       |          | YES                            | NO |
|  | B01 | EP 0 792 654 A2 | 9/3/1997 | Europe  |       |          | *X                             |    |
|  | B02 | WO 89/04674     | 6/1/1989 | PCT     |       |          |                                |    |
|  |     |                 |          |         |       |          |                                |    |
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|  |     |                 |          |         |       |          |                                |    |

**OTHER REFERENCES** (Including Author, Title, Date, Pertinent Pages, Etc.)

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|  | C01 | F. Kandziora et al., "Experimentelle Spondylodese der Schafshalswirbelsäule," <u>Der Chirurg</u> , 2002, 73:1025-1038.  |
|  | C02 | M. Lucke et al., "Gentamicin coating of metallic implants reduces implant-related osteomyelitis in rats," <u>Bone</u> , 32 (2003), pp 521-531.  |
|  | C03 | H. Bail et al., "Systemic application of growth hormone enhances the early healing phase of osteochondral defects-a preliminary study in micropigs," <u>Bone</u> , 32 (2003), pp 457-467.   |
|  | C04 | G. Schmidmaier et al., "Bone Morphogenetic Protein-2 Coating of Titanium Implants Increases Biomechanical Strength and Accelerates Bone Remodeling in Fracture Treatment: A Biomechanical and Histological Study in Rats," <u>Bone</u> , Vol. 30, No. 6, June 2002:816-822. |
|  | C05 | B. Wildemann et al., "Cell Proliferation and Differentiation During Fracture Healing Are Influenced by Locally Applied IGF-1 and TGF- $\beta$ 1: Comparison of Two Proliferation Markers, PCNA and BrdU," 2003 <u>Wiley Periodicals, Inc.</u> , pp 150-156.                 |
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|  | C07 | F. Kandziora et al., "IGF-I and TGF- $\beta$ 1 Application by a Poly-(D,L-Lactide)-Coated Cage Promotes Intervertebral Bone Matrix Formation in the Sheep Cervical Spine," <u>SPINE</u> , Volume 27, Numer 16, pp 1710-1723, 2002.  |
|  | C08 | F. Kandziora et al., "Bone morphogenetic protein-2 application by a poly(D,L-lactide)-coated interbody cage: in vivo results of a new carrier for growth factors," <u>J Neurosurg (Spine 1)</u> , 97:40-48, 2002.   |
|  | C09 | G. Schmidmaier et al., "Improvement of Fracture Healing by Systemic Administration of Growth Hormone and Local Application of Insulin-like Growth Factor-1 and Transforming Growth Factor- $\beta$ 1," <u>Bone</u> , Vol. 31, No. 1, July 2002:165-172.                     |
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|  | C13 | M. Raschke et al., "Homologous Growth Hormone Accelerates Healing of Segmental Bone Defects," <u>Bone</u> , Vol. 29, No. 4, October 2001:368-373.   |
|  | C14 | G. Schmidmaier et al., "A New Electrochemically Graded Hydroxyapatite Coating for Osteosynthetic Implants Promotes Implant Osteointegration in a Rat Model," 2002 <u>John Wiley &amp; Sons, Inc.</u> , pp 168-172.  |
|  | C15 | F. Kandziora et al., "Comparison of BMP-2 and combined IGF-1/TGF- $\beta$ 1 application in a sheep cervical spine fusion model," <u>Eur Spine J</u> , (2002), 11:482-493.   |
|  | C16 | G. Schmidmaier et al., "Local Application of Growth Factors (Insulin-Like Growth Factor-1 and Transforming Growth Factor- $\beta$ 1) From a Biodegradable Poly(D,L-lactide) Coating of Osteosynthetic Implants Accelerates Fracture Healing in Rats," <u>Bone</u> , Vol. 28, No. 4, April 2001:341-350. |
|  | C17 | G. Schmidmaier et al., "Biodegradable Poly(D,L-Lactide) Coating of Implants for Continuous Release of Growth Factors," 2001 <u>John Wiley &amp; Sons, Inc.</u> , pp 449-455.  |

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| EXAMINER | DATE CONSIDERED |
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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